

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of : Attorney Docket No. 2005\_0097A  
Katsumi IHARA et al. :  
Patent No. 7,815,932 :  
Issued October 19, 2010 :  
PATCH CONTAINING FENTANYL FOR :  
MUCOUS MEMBRANE OF ORAL CAVITY :

---

**PETITION REGARDING PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. § 1.705(d), the Patentee hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of **822 days**. This Petition is being filed within two months of the Issue Date (October 19, 2010), as required by 37 C.F.R. § 1.705(d).

I. Fee

As required by 37 C.F.R. § 1.705(b)(1), this Petition is accompanied by the required fee of \$200.00.

II. Statement of the Facts Involved

A. Correct Patent Term Adjustment

The Issue Notification, which was mailed on September 29, 2010, indicated a Patent Term Adjustment of 769 days.

Patentee has calculated a Patent Term Adjustment of **822 days** based on the following facts:

#### B. Relevant Dates

The above identified application has a 35 U.S.C. § 371 filing date of February 9, 2005.

The first Office Action was mailed on January 11, 2008, resulting in a PTO delay of 642 days beyond the 14 months provided by 35 U.S.C. § 154(b).

A Response by the Patentee was filed July 10, 2008, resulting in a Patentee delay of 90 days beyond the 3 months provided by 35 U.S.C. § 154(b).

A final Office Action was mailed October 14, 2008, within the 4 months provided by 35 U.S.C. § 154(b).

A Response by the Patentee, together with a Notice of Appeal, was filed April 13, 2009, resulting in a Patentee delay of 89 days beyond the 3 months provided by 35 U.S.C. § 154(b).

A Supplemental Response by the Patentee was filed April 17, 2009, resulting in a Patentee delay of 4 additional days beyond the 3 months provided by 35 U.S.C. § 154(b). Please also see 37 C.F.R. § 1.704(c)(8).

An Advisory Action was mailed April 27, 2009, and a Request for Continued Examination by the Patentee was filed June 5, 2009.

A non-final Office Action was mailed September 2, 2009, within the 4 months provided by 35 U.S.C. § 154(b).

A response by the Patentee was filed January 29, 2010, resulting in a Patentee delay of 58 days beyond the 3 months provided by 35 U.S.C. § 154(b).

An Information Disclosure Statement was filed April 19, 2010, resulting in a Patentee delay of 80 days, in accordance with 35 U.S.C. § 154(b) and 37 C.F.R. § 1.704(c)(8).

An Information Disclosure Statement was filed June 4, 2010 together with a statement under 37 C.F.R. § 1.704(d), and therefore resulting in no Patentee delay under 35 U.S.C. § 154(b).

A Notice of Allowance was mailed June 14, 2010, resulting in a PTO delay of 16 days beyond the 4 months provided by 35 U.S.C. § 154(b).

The Issue Fee was paid on September 1, 2010, within the 3 months provided by 35 U.S.C. § 154(b).

The patent issued on October 19, 2010, within the 4 months provided by 35 U.S.C. § 154(b).

Accordingly, the PTO adjustment based on delay under 35 U.S.C. § 154(b)(1)(A) is 642 + 16 = 658 days.

The 35 U.S.C. § 154(b)(1)(B) period for the instant application began on February 9, 2008 (three years after the filing date of February 9, 2005) and ended the day prior to the filing of the Request for Continued Examination (June 4, 2009). Thus, the 35 U.S.C. § 154(b)(1)(B) period running from February 9, 2008 until June 4, 2009 is 485 days.

There were 0 days of PTO delay under 35 U.S.C. § 154(b)(1)(A) that overlap with the 35 U.S.C. § 154(b)(1)(B) period that should be excluded from the patent term adjustment calculation under the holding of *Wyeth v. Kappos*, 2010 U.S. App. Lexis 300.

There were  $90 + 89 + 4 + 58 + 80 = 321$  days of Patentee delay under 35 U.S.C. § 154(b)(2)(C).

Accordingly, the sum of the 35 U.S.C. § 154(b)(2)(B) delay (485 days) and 35 U.S.C. § 154(b)(2)(A) delay (658 days) less the overlap days (0 days) and less Patentee delay days (321 days) results in a PTA of **822 days**.

However, the PTA printed on the Issue Notification is only 769 days. Patentee therefore respectfully requests reconsideration of the PTA calculation.

#### C. Terminal Disclaimer

The above-identified patent is not subject to a Terminal Disclaimer.

#### D. Reasonable Efforts

Any Patentee delays under 37 C.F.R. § 1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

Based upon the provisions of 37 CFR 1.705(d), and for the reasons provided in detail above, Patentee respectfully requests correction of the Patent Term Adjustment in the above-identified patent to **822 days**.

Respectfully submitted,

Katsumi IHARA et al.

/Amy E. Schmid/

By 2010.11.03 10:26:49 -04'00'

Amy E. Schmid  
Registration No. 55,965  
Attorney for Patentee

AES/cbc  
Washington, D.C. 20005-1503  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
November 3, 2010